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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,973	12/09/2003	Eric R. First	17637 (BOT)	6433

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EXAMINER	
TONGUE, LAKIA J	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 12/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/731,973	FIRST, ERIC R.	
	Examiner	Art Unit	
	Lakia J. Tongue	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 8-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed on September 19, 2005 is acknowledged. Claims 1-6, 8-11 and newly added claim 12 are pending and under consideration. Claim 7 has been canceled.

The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

Objections Withdrawn

1. In view of applicant's response, the objection to the information disclosure statement is withdrawn.

Rejections Maintained

2. The rejection of claims 1-6 and 9 and 1-6 and 10 under 35 U.S.C. 102(b) as being anticipated by Binder (U.S. Patent 5,670,484 and EP 0 845 267 B1) are maintained for the reasons set forth in the previous Office Action page 11, paragraph 4 and page 13, paragraph 5.

The rejection was on the ground that Binder discloses (1) a method for mitigating or inducing remission of a skin lesion associated with a cutaneous cell-proliferation disorder in a mammal comprising administering a therapeutically effect amount of a Botulinum toxin in a pharmaceutically safe form to the mammal by delivery of the Botulinum toxin to the site of the lesion. (2) The method according to claim 1 wherein the Botulinum toxin is administered by subcutaneous injection. (3) The method

according to claim 1 wherein the Botulinum toxin is Botulinum toxin A (column 9, line 13). Binder shows that Botulinum toxin A has the ability to reduce the number, severity and/or frequency of appearance of lesions and associated discomfort experienced by the patient suffering from primary cutaneous disorders such as psoriasis and dermatitis (column 4, line 10). Discomfort is defined as: state of physical unease: very mild pain or a feeling of being physically uncomfortable (Encarta® World English Dictionary [North American Edition] © & (P) 2004 Microsoft Corporation. Binder further teaches the serotypes of Botulinum toxin B, C1, C2, D, F and G (column 2, line 43). Additionally, Binder teaches a preferred administration of individual dosages of about 5-15 units (column 5, line 39).

The rejection was on the ground that Binder teaches an invention relates to the use of a neurotoxin for a medicament treating cutaneous cell-proliferate disorders. Specifically, the invention comprises the use of a therapeutically effective and pharmaceutically safe neurotoxin. The medicament will preferably be for the subdermal or sub-cutaneous administration, but may also be used for topical and transdermal routes of administration (page 3, section 0016, line 30). Binder shows the preferred neurotoxin of the invention is Botulinum toxin A (page 3, section 0018, line 38). Additionally, Binder shows the target tissue for administration of a neurotoxin according to the invention is skin. "Skin" as used on the disclosure shall refer to the tissue comprised of epidermal, dermal, subdermal and subcutaneous layers of cells (page 3, section 0019, line47). Lastly, Binder teaches that the method of the invention can be expected to be effective in mitigating lesions (e.g., by reducing their size or incidence) (page 5,section 0035, line 27).

Applicant urges that a) the lesion disclosed by the Binder reference is not an equivalent of the "ulcer" feature of the present claims and b) Binder does not disclose the step of diagnosing/identifying a patient with warts and thereby administering botulinum toxin to treat the warts.

It is the examiner's position that the claims are drawn to a method for treating a skin disorder to a patient in need thereof, the method comprising the steps of administering a therapeutically effective amount of a botulinum toxin to a location of a skin disorder of the patient, wherein the skin disorder comprises a disorder selected from a group consisting of warts, corns, neuromas, ulcers, hammertoes and bunions, thereby treating the skin disorder. An ulcer is defined as a lesion through the skin or a

mucous membrane resulting from loss of tissue, usually with inflammation (Stedman's online dictionary). Binder discloses a method of administering a therapeutically effective amount of botulinum toxin to an ulcer. The examiner has likened lesion to ulcer, which is supported by the definition of ulcer and has been attached to this office action. The examiner acknowledges the exhibits that have been provided by applicant and notes that applicant is arguing points that are not present in the instant claim language. Moreover, Binder discloses a method for the treatment of skin lesions. While the Binder reference does not explicitly teach the step of diagnosing a patient in need thereof, one of skill in the art would understand that such diagnosis would have already been made and that the method disclosed in Binder would have been a proper treatment for a skin disorder based on that diagnosis.

3. The rejection of claim 11 under 35 U.S.C. 102(e) as being anticipated by Kwon (U.S. 2004/0087893 A1) is maintained for the reasons set forth in the previous Office Action page 7, paragraph 8.

The rejection was on the grounds that Kwon disclose a method of administering a safe and efficient amount of botulinum toxin for treating lesions or abnormal skin features, such as pimples, corns, warts, calluses and bunions (page 6, section 0077). The specification has characterized a therapeutically effective amount as an amount to alleviate a symptom of a skin disorder (page 21), inherently Kwon has administered a therapeutically amount of botulinum toxin.

Applicant urges that a) Kwon does not disclose a method of administering a botulinum toxin for treating warts, b) Kwon discloses a solid drug solution perforator (SSP) system and an associated drug reservoir for delivering therapeutic, prophylactic and/or cosmetic compounds, for nutrient drug delivery and for drug targeting and merely

suggest that the claimed system may be used in combination with a drug to treat warts, c) Kwon only teaches the botulinum toxin can be delivered by the SSP system "to remove or reduce wrinkle formation and skin aging" and d) Kwon does not teach or suggest that botulinum toxin may be administered to treat warts.

It is the examiner's position that the claims are drawn to a method for treating a wart in a patient in need thereof, the method comprising the steps of administering a therapeutically effective amount of a botulinum toxin to a location of a wart, thereby treating the wart. Moreover, the instantly claimed invention does not exclude any device present to carry out the method for treating a skin disorder. Kwon discloses a method for the treatment of skin disorders, particularly lesions or abnormal skin features, pimples, corns, warts, calluses, bunions, actinic keratoses and hard hyperkeratotic skin (0077).

New Grounds Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 12 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The response filed September 19, 2005 has introduced NEW MATTER into the claims. Newly added claim 12 recites "dermatofibroma, keloid, mole, granuloma and keratose." The response did not point out where support for newly added claim 12 could be found in the originally filed disclosure. Although the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims, when filing an amendment an applicant should show support in the original disclosure for new or amended claims. See MPEP 714.02 and 2163.06 ("Applicant should therefore specifically point out the support for any amendments made to the disclosure."). Instant claim 12 now recites limitations, which were not clearly disclosed in the specification as filed. Such limitations recited in newly added claim 12, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C 112. Applicant is required to point to written description support for the limitations recited in present claim 12 in the specification or claims, as-filed, or remove these limitations from the claims in response to this Office Action.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakia J. Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LJT

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